

MAY 10 1999



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Margaret Brumm
Eli Lilly and Company
Patent Division/MMB
Lilly Corporate Center
Indianapolis, IN 46285

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,808,614

#21

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,808,614, which claims the human drug product GEMZAR® (gimcitabine), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,537 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,537 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 3, 1998 (63 Fed. Reg. 41263). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,824 - 658) + 469 \\ &= 1,552 \text{ days}\end{aligned}$$

Since the regulatory review period began May 12, 1987, before the patent issued (February 28, 1989), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From May 12, 1987 to February 28, 1989 is 658 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,552 days, would extend the patent from February 28, 2006 to May 30, 2010, which is beyond the 14-year limit (the approval date is May 15, 1996, 14 years after the approval date is May 15, 2010). The period of extension is thus limited to May 15, 2010, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, February 28, 2006, to and including May 15, 2010, or 1,537 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

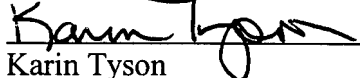
Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,808,614
Granted:	February 28, 1989
Original Expiration Date:	February 28, 2006
Applicant:	Larry W. Hertel
Owner of Record:	Eli Lilly and Company
Title:	Difluoro Antivirals and Intermediate Therefor
Classification:	514/45
Product Trade Name:	GEMZAR® (gimcitabine)
Term Extended:	1,537 days
Expiration Date:	May 15, 2010

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Assistant Commissioner for Patents	By FAX: (703) 308-6916
	Box Patent Ext.	Attn: Special Program Law Office
	Washington, D.C. 20231	

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.


Karin Tyson
Senior Legal Advisor/Special Program Law Office

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: GEMZAR® (gimcitabine)
FDA Docket No.: 96E-0314